

ATTACHMENT A Remarks

Claims 1, 2, 4-6 and 8-10 are pending in the present application. By this Amendment, Applicants have amended claims 1 and 4. Applicants respectfully submit that upon entrance of the present amendment, the application will be placed in condition for allowance based on the discussion which follows.

Claims 1, 2 and 4-6 were rejected under 35 U.S.C. § 102(b) as being anticipated by EP 0395300 (hereinafter "EP '300") or Rigby et al (hereinafter "Rigby"). In addition, claims 1, 2, 4-6 and 8-10 were rejected under 35 U.S.C. § 102(b) as being anticipated by Aurenius.

In the outstanding Office Action, it was stated that the claimed largest external dimension of the support being less than 100 microns is interpreted as claiming a support have one dimension which is less than 100 microns, not the entire device having all dimensions less than 100 microns.

Applicants respectfully submit that the interpretation of claim 1 with regard to the largest external dimension of the support being less than 100 microns is taken completely out of context as the claimed solid support exists in three dimensional space thus having three dimensions as does the prior art. Therefore, any prior device with <u>any</u> dimension greater than 100 microns is outside the claim scope. Moreover, the claim clearly requires that the support be substantially linear or planar in shape. With such a shape, the largest external dimension by definition must lie in the case of a substantially linear support, along its length, and in the case of a substantially planar support, in the plane of the support. However, in order for there to be absolutely no ambiguity, claim 1 has been amended to clarify this apparent requirement.

Further, Applicants respectfully submit that the amendment to claim 1 should be entered because the amendment makes the claims more commensurate with the arguments presented in the previously filed Amendments. Moreover, the amendments do not raise new issues for consideration and no additional prior art search needs to be conducted as the Examiner has stated in the outstanding Office Action that he has examined the claims as argued and now recited. Therefore, upon entrance of the present Amendment, all elements of the currently pending claims have been searched and considered, and thus, this amendment does not raise new issues for consideration. Finally, the present claim amendments place the application in proper condition for allowance, provide a complete application file history, and enhance the clarity of the prosecution record and place the claims in better condition for appeal. Therefore, the amendment is proper for entrance after final.

Applicants respectfully submit that although EP '300, Rigby and Aurenius may each teach a layer having a thickness of less than 100 microns, that is not relevant to the novelty of claim 1 as the prior art dimension which is less than 100 micron is not the largest external dimension of each of these layers in the plane of the respective layer. Moreover, these dimensions are either explicitly stated as either being significantly larger than 100 microns or will inevitably be significantly larger than that. That is:

(i) EP '300 discloses a thin film device having layers which generate a color response capable of detecting organic material. However, the device is visible to the eye and so each layer clearly extends to macroscopic dimensions in all directions in the plane of <u>the layer</u>.

- (ii) Rigby discloses a production method for microfiltration membranes.

 These membranes will again clearly extend to macroscopic dimensions in all directions in the plane of the membrane.
- (iii) Aurenius discloses square planar microlabels which have a smallest dimension in the plane of the label of about 1 mm.

Thus, claim 1 is novel over each of EP '300, Rigby and Aurenius.

Furthermore, the prior art fails to teach or suggest a solid support structure which must provide for forming an aqueous suspension as claimed. The prior art of EP '300, Rigby and Aurenius devices are unsuitable for forming an aqueous suspension as claimed. In order to more clearly recite the claimed solid support, claim 1 has been amended to recite that the aqueous suspension is for performing a bioassay. The prior art fails to teach a solid support which has the structure to be able to perform as claimed. Referring to the prior art:

The thin films of EP '300 are formed on glass or plastic substrates 11.

There is no teaching to detach the films from the substrates, and moreover the size of the films precludes them from being used to form an aqueous suspension for performing a bioassay. EP '300 does teaches (page 5, lines 22-23) that, "the device can be dipped into a sample fluid, or a drop of the fluid can be dropped onto the porous surface of the device.

After an appropriate time to allow binding to take place, the sample fluid can be washed off and the device allowed to dry", but this mode of operation does not suggest in any way the use of a suspension of a plurality of the EP '300 devices for the purposes of a bioassay.

- (ii) Likewise, Rigby's microfiltration membranes are clearly too large to form an aqueous suspension for performing a bioassay.
- (iii) As to Aurenius, we previously distinguished the prior claimed invention by arguing that the microlabels disclosed therein are not suitable for forming aqueous suspension biochemical assays, and this argument is reinforced by the clarification in claim 1 (currently amended) that the suspension is "for performing a bioassay".

Thus further novelty of claim 1 over EP '300, Rigby and Aurenius resides in the requirement that the support is capable of forming an aqueous suspension for performing a bioassay.

Moreover, EP '300 and Rigby, in particular, fail to teach or suggest the claimed incorporation of a spatially varying pattern for identification purposes of the claimed support.

That is, EP '300 and Rigby contain no disclosure of such a pattern relative to their respective layers/membranes. More specifically, neither the top anodised layer 14 of EP '300 nor the anodised film of Rigby's microfiltration membranes have a spatially varying pattern that could be used for identification purposes.

For the foregoing reasons, Applicants respectfully submit that claims 1-2, 4-6 and 8-10 are not anticipated by EP '300, Rigby or Aurenius.

Furthermore, although the Examiner suggests in the "Response to Arguments" section of the outstanding Office Action that the present less than 100 micron dimension for the largest external dimension of a support would be obvious in view of the prior art, Applicants respectfully submit that the presently claimed solid support is more than

mere miniaturization of the cited prior art devices. For example, the present invention has inherent properties and performs inherent functions directly resulting from the claimed structure which the prior art fails to teach or suggest in its current disclosed form. Moreover, even if the skilled person were to somehow be motivated to reduce the size of the devices disclosed in the prior art, the resulting device would fail to have the claimed features of the presently claimed device. For example, none of EP '300, Rigby and Aurenius relates to supports which are to be used to form an aqueous suspension for performing a bioassay.

Moreover, mere miniaturization is not the reason why a maximum size is imposed on the support of the present invention. Rather the support's size critically affects its functionality and hence its fitness for purpose. Thus the present invention concerns the selection of the size (and shape and structure and materials) of solid supports, e.g., particulate supports, in order to allow the supports to form a suspension for a bioassay. Such an assay cannot be performed "dry", but must be done aqueously. Much better mixing of the analyte and the biochemical test reagent attached to the supports is obtained if freely floatable supports are used (i.e. the support are suspensed) rather than having the test reagent attached to a large and effectively immobile support or to a flat surface. Also a fundamental change in reaction rates occurs, which is probably related to diffusion lengths/times, when the support particles are sufficiently small.

Thus the requirement for the largest external dimension of the support of claim 1 to be less than 100 µm is not arbitrary, but a size limit below which it becomes possible

to form an aqueous suspension of particles for performing an effective biochemical assay. Therefore, in view of the prior art the present claims are not obvious.

Based on the foregoing, Applicants respectfully submit that claims 1-2, 4-6 and 8-10 are not obvious in view of EP '300, Rigby and Aurenius.

Claims 1-2, 4-6 and 8-10 were rejected under 35 U.S.C. § 102(b) as being anticipated by GB 2306484 (hereinafter "GB '484") or WO 97/12680 (hereinafter "WO '680"). With regard to the subject matter of claim 1, GB '484 and WO '680 fail to teach or suggest an <u>anodized</u> metal surface layer on the solid support. Although GB '984 and WO '680 teach an aluminum layer, they do not teach an <u>anodized</u> metal layer.

The Examiner had alleged that the GB '484 and WO '680 aluminum layer is equivalent to the claim anodized layer of claim 1 because Applicants, in claim 4 recite that the anodized layer of claim 1 can be aluminum, and thus falsely concluding that Applicants somehow consider conventional aluminum to be an anodized material. Contrary to this illogical and incorrect interpretation, claim 4 merely reflects that the anodized layer in Claim 1 can be anodized aluminum, and does not reflect that the layer of Claim 1 could be a non-anodized metal. So there will be absolutely no ambiguity as to this already clear interpretation, by this Amendment, Applicants have now amended claim 4 to recite the surface layer is of anodized aluminum, although this was obviously the only possible interpretation of the claim in the first instance. Applicants respectfully submit that GB '484 and WO '680 fail to teach or suggest an anodized metal layer recited in claim 1 as the disclosed aluminum layer in the prior art is clearly not equivalent to the claimed anodized layer. Therefore, Applicants respectfully submit that

claims 1, 2, 4-6, and 8-10 are not anticipated or made obvious by GB '484 and WO '680.

Based on the foregoing, Applicants respectfully submit that claims 1, 2, 4-6 and 8-10 are not anticipated by GB '484 or WO '680.

In view of the foregoing, Applicants respectfully submit that entrance of the present amendment will place of the claims in condition for allowance, and thus entrance of the amendment and allowance of the application is respectfully requested.

END REMARKS